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Judith U. Kim Timothy J. Shea, Jr. Patrick E. Garrett Jeffrey T. Helvey Heidi L. Kraus Albert L. Ferro* Donald R. Ranowit Peter A. Jackman Teresa U. Medler Jeffrey S. Weaver Kendrick P. Patterson Vincent L. Capuano Eldora Ellison Floyd Thomas C. Fiala Theodore A. Wood Elizabeth J. Haanes

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*Admitted only in Maryland *Admitted only in Virginia *Practice Limited to Federal Agencies

July 27, 2004

WRITER'S DIRECT NUMBER: (202) 772-8615 INTERNET ADDRESS: FRANKC@SKGF.COM

Art Unit 1615

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Utility Patent Application

Application No. 09/972,913; Filed: October 10, 2001

Use of Clioquinol for the Therapy of Alzheimer's Disease

Inventors:

BUSH et al.

Our Ref:

0609.4540003/TJS/FRC

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. Fee Transmittal Form (PTO/SB/17);
- 2. Information Disclosure Statement;
- 3. Listing of the cited documents on Form PTO-1449 (55 sheets);
- 4. A copy of five (5) of the cited documents on Form PTO-1449;
- 5. Credit Card Payment Form (PTO-2038) in the amount of \$180.00 to cover the IDS fee; and
- 6. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Sterne, Kessler, Goldstein & Fox PLL.c.: 1100 New York Avenue, NW: Washington, DC 20005: 202.371.2600 f 202.371.2540: www.skqf.com

Commissioner for Patents July 27, 2004 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Frank R. Cottylun

Frank R. Cottingham Attorney for Applicants Registration No. 50,437

FRC/pcd Encls.

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Effective 10/01/2003. Patent fees are subject to annual revision.

X Applicant claims small entity status. See 37 CFR 1.27

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Name (Print/Type)

Signature

Frank R. Cottingham

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Filing Date	October 10, 2001	111 0 7 000¢
First Named Inventor	Ashley I. BUSH	30L 2 / 2004 11
Examiner Name	Sheikh, H.	2. 8
Art Unit	1615	RADEMARK
Attorney Docket No.	0609.4540003/TJS/FR	C

METHOD OF PAYMENT (check all that apply)	FEE CALCULATION (continued)					
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Number Deposit	1051	130	2051		Surcharge - late filing fee or oath	
Account Sterne, Kessler, Goldstein & Fox P.L.L.C.	1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
Name The Director is authorized to: (check all that apply)	1053	130	1053	130	Non-English specification	
X Charge fee(s) indicated below	1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
X Charge any additional fee(s) or any underpayment of fee(s)	1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.	1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
FEE CALCULATION	1251	110	2251	55	Extension for reply within first month	
1. BASIC FILING FEE	1252	420	2252	210	Extension for reply within second month	
Large Entity Small Entity	1253	950	2253	475	Extension for reply within third month	
Fee Fee Fee Fee Fee Paid Code (\$) Code (\$)	1254	1,480	2254	740	Extension for reply within fourth month	
1001 770 2001 385 Utility filing fee	1255	2,010	2255	1,005	Extension for reply within fifth month	<u> </u>
1002 340 2002 170 Design filing fee	1401	330	2401	165	Notice of Appeal	
1003 530 2003 265 Plant filing fee	1402	330	2402	165	Filing a brief in support of an appeal	
1004 770 2004 385 Reissue filing fee	1403	290	2403	145	Request for oral hearing	
1005 160 2005 80 Provisional filing fee	1451	1,510	1451	1,510	Petition to institute a public use proceeding	
SUBTOTAL (1) (\$)	1452	110	2452		Petition to revive - unavoidable	
	1453	1,330	2453	665	Petition to revive - unintentional	
2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE	1501	1,330	2501	665	Utility issue fee (or reissue)	
Extra Claims below Fee Paid	1502	480	2502	240	Design issue fee	
Total Claims 20 **=	1503	640	2503	320	Plant issue fee	
Claims — 3 = — X — — 1	1460	130	1460	130	Petitions to the Commissioner	
Multiple Dependent	1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
Large Entity Small Entity Fee Fee Fee Fee Fee Description	1806	180	1806	180	Submission of Information Disclosure Stmt	180.00
Fee Fee Fee Fee <u>Fee Description</u> Code (\$) Code (\$)	8021	40	8021	40	Recording each patent assignment per	
1202 18 2202 9 Claims in excess of 20	1809	770	2809	205	property (times number of properties) Filing a submission after final rejection	
1201 86 2201 43 Independent claims in excess of 3	1009	770	2003	303	(37 CFR 1.129(a))	
1203 290 2203 145 Multiple dependent claim, if not paid	1810	770	2810	385	For each additional invention to be	
1204 86 2204 43 ** Reissue independent claims over original patent	1801	770	2801	205	examined (37 CFR 1.129(b))	
1205 18 2205 9 ** Reissue claims in excess of 20	1801	900	1802	385 900	(,	
and over original patent	1002	300	1002	300	of a design application	
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**or number previously paid, if greater; For Reissues, see above	*Redu	ced by	Basic I	Filing F	ee Paid SUBTOTAL (3) (\$)	180.00
SUBMITTED BY					(Complete (if applicable))	

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Registration No.

Telephone

Date

50,437

(202) 371-2600

July 27, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Bush et al.

Appl. No. 09/972,913

Filed: October 10, 2001

For: Use of Clioquinol for the

Therapy of Alzheimer's Disease

Confirmation No. 5681

Art Unit:

1615

Examiner:

Sheikh, H.

Atty. Docket: 0609.4540003/TJS/FRC

Information Disclosure Statement

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450 Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents AF1, AG1, AH1, AI1 and AJ1 are submitted herewith. Copies of all other documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/224,953, Bush et al., filed January 4, 1999, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Form PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. Attached is our PTO-2038 Credit Card Payment Form in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Frank R. Cottingham Attorney for Applicants Registration No. 50,437

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Date: July 27, 2004 1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600 Page 1 of 55

WTTY. DOCKET NO. APPLICATION NO. 09/972,913

FIRST NAMED INVENTOR

Page 1 of 55

09/972,913

Bush et al. INFORMATION DISCLOSURE STATEMENT ART UNIT **FILING DATE** October 10, 2001 1615 U.S. PATENT DOCUMENTS **EXAMINER** CLASS SUB-CLASS FILING DATE INITIAL DOCUMENT NUMBER DATE NAME 04/26/1993 5,373,021 12/13/1994 Marangos AA1 Raad et al. 10/03/1994 AB1 5,688,516 11/18/1997 AC1 5,688,651 11/18/1997 Solomon 12/16/1994 01/06/1998 | Masters et al. 09/16/1994 AD1 5,705,401 AE1 5,721,106 02/24/1998 Maggio et al. 09/12/1994 AF1 5,980,914 11/09/1999 Gerolymatos 02/13/1998 5,994,323 11/30/1999 02/13/1998 AG1 Gerolymatos 6,001,852 12/14/1999 Gerolymatos 02/13/1998 AH1 AI1 6,323,218 11/27/2001 Bush et al. 03/11/1998 Bush et al. 09/21/2001 AJ1 2002/0082273 06/27/2002 ΑK FOREIGN PATENT DOCUMENTS **EXAMINER** INITIAL DOCUMENT NUMBER DATE COUNTRY CLASS SUB-CLASS TRANSLATION WO 92/18111 10/29/1992 **WIPO** AL1 No Yes AM1 WO 93/10459 05/27/1993 **WIPO** No Yes WO 93/24451 12/09/1993 **WIPO** ANI No Yes 03/03/1994 WIPO AO1 WO 94/04167 No Yes AP1 WO 95/31199 11/23/1995 WIPO No OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Assaf, S.Y., and Chung, S-H., "Release of endogenous Zn²⁺ from brain tissue during AR 1 activity," Nature 308:734-736, Nature Publishing Group (April 1984) Atwood, C.S., et al., "Dramatic Aggregation of Alzheimer A β by Cu(II) Is Induced by Conditions Representing Physiological Acidosis," J. Biol. Chem. 273:12817-12826, AS 1 American Society for Biochemistry and Molecular Biology (May 1998) Bacon, P.A., et al., "Rheumatoid Disease, Amyloidosis and its Treatment with ΑT 1 Penicillamine," Eur. J. Rheum. Inflamm. 2:70-74, Cameron Publishers (1979)

FORM PTO-1449

EXAMINER DATE CONSIDERED

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

considered. Include copy of this form with next communication to Applicant.

Page 2 of 55 APPLICATION NO.

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0609.4540003/TJS/FRC 09/972,913 FIRST NAMED INVENTOR

Bush et al.

FILING DATE
October 10, 2001

ART UNIT 1615

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	AL2	W	O 96/07096	03/07/1996	WIPO			Yes No
	AM2	W	O 96/12544	05/02/1996	WIPO			Yes No
	AN2	W	0 96/28471	09/19/1996	WIPO			Yes No
	AO2	W	O 97/04794	02/13/1997	WIPO			Yes No
	AP2	W	O 97/09976	03/20/1997	WIPO			Yes No
	•		OTHER (Incl	uding Author	, Title, Date, Pertinent Pages,	etc.)		
	AR	2		ition to Amylo	1.G., "Solution Structures of oid Deposition," <i>Science 253</i> ace (July 1991)			
	AS	2	Barrow, C.J., et Amyloid β-Pept (June 1992)					
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	Page 3 of 33
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	AL3	WO 97/36885	10/09/1997				Yes		
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	AR	Behl, C., <i>et al.</i> 77:817-827, Ce		eroxide Mediates Amyloid β 1994)	Protein 7	Γοχίσιτy," C	ell		
	AS	3 Molecular Oxy	Biaglow, J.E., and Kachur, A.V., "The Generation of Hydroxyl Radicals in the Reaction of Molecular Oxygen with Polyphosphate Complexes of Ferrous Ion," <i>Radiat. Res.</i> 148:181-187, Kluge Carden Jennnings Pub. Co. (August 1997)						
	AT	3 Alzheimer's Di	sease and Cer	livery of Antisense Moleculo ebral AIDS," <i>J. Pharm. Sci.</i> November 1998)					
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FIRST NAMED INVENTOR

Bush et al.

FILING DATE October 10, 2001 ART UNIT 1615

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	AS	5		's Syndrome	B.A., "Apoptosis and increate neurons in vitro," Nature			
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ATTY. DOCKET NO.
0609.4540003/TJS/FRC

FIRST NAMED INVENTOR
Bush et al.

FILING DATE
October 10, 2001

Page 6 of 55

APPLICATION NO.
09/972,913

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AR 8 Cherny, R.A., et al., "The Aggregation of Aβ in Human Brain is Mediated by Zinc," Abs. Soc. Neurosci. 23:534, Society For Neuroscience (October 1997)	bstr.
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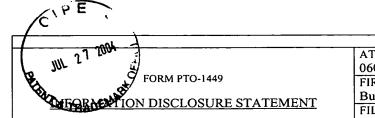
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				ge, J.M.C., and Wilkins, S., "Copper Salt-Dependent Hydroxyl Radical Formation to Proteins Acting as Antioxidants," <i>Biochim. Biophys. Acta</i> 759:38-41, Elsevier 1983)					
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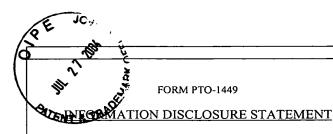
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	AS	<u>20</u>	Harman, D., "Aging: A Theory Based on Free Radical and Radiation Chemistry," J. Gerontol. 2:298-300, Gerontological Society Of America (July 1956)						
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	AT	23	Blood by a New	ly Develo	f Heterogeneous βA4 ped Sensitive Wester for Biochemistry and	n Blot Assa	y," <i>J. Bi</i>	ol. Chem. 27	71:22908-	
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	AS	25	Kang, J., et al., "The precursor of Alzheimer's disease amyloid A4 protein resembles a cell-surface receptor," <i>Nature 325:733-736</i> , Nature Pub. Co. (February 1987)					
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	AT	<u>26</u>	Kirschner, D.A. forms amyloid-l Academy of Sci	ike fibrils in	thetic peptide homologou vitro," Proc. Natl. Acad. per 1987)	s to β protein Sci. USA 84:	from Alzhe 6953-6957,	imer disease National		
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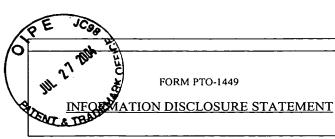
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	AS	27	Kisilevsky, R., 'Humana Press (tion-Associated Amylo 994)	idogenesis," <i>Mol</i> .	Neurobiol.	8:65-66,
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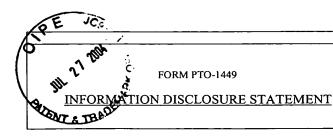
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